

# **EXHIBIT J**

**UNITED STATES BANKRUPTCY COURT  
DISTRICT OF MASSACHUSETTS  
EASTERN DIVISION**

In re:  NEW ENGLAND COMPOUNDING PHARMACY, INC.,  Debtor.	Chapter 11  Case No. 12-19882-HJB
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**DECLARATION OF GREGORY EARL THOMAS IN SUPPORT OF  
CONFIRMATION OF FIRST AMENDED JOINT CHAPTER 11 PLAN  
OF NEW ENGLAND COMPOUNDING PHARMACY, INC.**

I, Gregory Earl Thomas, submit this declaration in support of confirmation of the Joint Chapter 11 Plan of New England Compounding Pharmacy, Inc. [Docket No. 1054] (as amended at Docket No. 1154 and thereafter from time to time, and including all exhibits and supplements thereto, the "Plan"), and respectfully state as follows:

1. I am the Vice President Business Development of ARL Biopharma, Inc. d/b/a Analytical Research Laboratories ("ARL"), and I am authorized to make this declaration on ARL's behalf.

2. ARL is a small, locally owned, Oklahoma corporation with its place of business in Oklahoma City, Oklahoma.

3. New England Compounding Pharmacy, Inc. ("NECC"), the debtor in the above captioned case, compounded and sold many different drugs. ARL provided limited testing services with respect to particular samples of some of the drugs NECC compounded and sold.

4. In the pending litigation against ARL, Plaintiffs allege that ARL (i) improperly tested NECC-compounded MPA bearing Lot Numbers 05212012@68, 06292012@26, and 08102012@51, which are the lot numbers associated with the NECC fungal meningitis outbreak;

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(ii) improperly tested NECC-compounded cardioplegia solution from unidentified “lots” or “batches,” which are alleged to have caused death; (iii ) declared those MPA and cardioplegia solution “lots” or “batches” to be “sterile” and within acceptable endotoxin levels when they were not; and (iv) thereby caused injury.

5. No evidence has been presented that ARL: (i) tested *any* final product from NECC Lot Numbers 05212012@68, 06292012@26, or 08102012@51, for sterility or endotoxins; (ii) tested *any* final product from any lot or batch of NECC-compounded cardioplegia solution allegedly causing injury; (iii) reported any NECC drug samples tested to be “sterile” or within acceptable endotoxin levels when they were not; or (iv) reported that “lots” or “batches” of any NECC-compounded product were “sterile” or within acceptable endotoxin levels. ARL only reported on the samples it tested.

6. Many of the claims made against ARL arise from injections given at facilities to which only 1 or 2 mL vials of NECC-compounded MPA were shipped. The evidence indicates that over 83% of the NECC MPA vials shipped bearing Lot Numbers 05212012@68, 06292012@26, and 08102012@51 were in 1 mL and 2 mL vials. ARL did not test any 1 or 2 mL vials of NECC-compounded MPA marked with the lot numbers implicated in the fungal meningitis outbreak, prior to September 26, 2012, the date of NECC’s MPA recall, let alone report they were “sterile” or within acceptable endotoxin levels. Despite facing allegations concerning endotoxin testing deficiencies, ARL is unaware of *any* injury allegedly caused by endotoxins. ARL is adamant that it is not liable to anyone for claims related to any NECC drugs.

7. ARL is included in the definition of “Other Contributing Parties” in the Plan and accordingly will, if the Plan is confirmed, be the beneficiary of certain releases and injunctions in aid thereof contained in the Plan.

8. I have been advised that courts in this and other Circuits, when evaluating third-party releases and injunctions (such as the Plan releases and injunctions in favor of ARL and others), consider such factors as (i) whether there is an identity of interest between the debtor and the third party, usually an indemnity relationship, such that a suit against the non-debtor is, in essence, a suit against the debtor or will deplete assets of the estate; (ii) whether the non-debtor has contributed substantial assets to the estate; and (iii) whether the Plan releases and injunction provided in the Plan are essential to the success and viability thereof and whether, without them, there is little likelihood of success. I respectfully submit that, with respect to the Plan releases and injunctions in favor of ARL, its affiliates, and its insurers, those factors are satisfied.

**A. There Is an Identity of Interest Between NECC and ARL.**

9. ARL has been made the subject of more than 200 lawsuits in both state and federal courts, including those consolidated in the MDL Proceeding, alleging personal injury or wrongful death due to the administration of NECC products. Further, ARL has received notices of intent to sue and other threats of litigation from hundreds of other potential plaintiffs. Accordingly, to the extent ARL is or becomes liable to any patient who received an injection of NECC MPA, ARL has strong and significant claims against NECC for, *inter alia*, contribution and indemnity. On January 10, 2014, ARL filed a proof of claim [Claim No. 63] against the NECC estate on those grounds. Absent confirmation of the Plan and the effectiveness of the releases and injunctions contained therein in favor of ARL and its affiliates, ARL intends to

pursue its claims against the NECC estate. There is plainly an identity of interest between NECC and ARL.

**B. ARL Has Contributed Substantial Assets to the Estate.**

10. In an effort to resolve ARL's claims against the NECC estate and the alleged claims of tort claimants against ARL, I, along with other management of ARL and its counsel participated in two days of mediation and extensive additional negotiation with the Trustee, his counsel, and representatives of both the Official Committee and the Plaintiffs' Steering Committee. The mediation and additional negotiations were supervised by Carmen Reiss of Resolutions LLC. After more than eight months of good faith, arm's-length negotiation, ARL and its insurer(s) Landmark American Insurance Company ("Landmark") agreed to contribute \$6.4 million to the NECC estate. This settlement amount represents the policy limits of ARL's Landmark coverage, plus other funds paid directly by ARL.

11. ARL agreed to participate in mediation in part to avoid the expense and delay of protracted litigation relating to ARL's alleged liability for the harm caused by NECC's products. That being said, ARL has strong legal and factual defenses to liability in connection with its alleged role in the outbreak.

a. The evidence to date indicates ARL did not test NECC final product. There is no evidence ARL tested any NECC samples that were actually contaminated and that it reported a false-negative result, i.e., reported a sample to be "sterile" when it was not, or reported a sample to be within acceptable endotoxin limits when it was not.

b. Further, no one can show i) that ARL tested final product from any of the lots of MPA implicated in the NECC fungal meningitis outbreak or cardioplegia solution;

ii) that *any* test ARL conducted yielded an inaccurate result; or iii) that any act or omission by ARL caused damage to NECC or to any NECC victim.

c. Finally, although ARL contended that the Landmark policy provides \$6.0 million in aggregate coverage, Landmark denied that the aggregate limit applies and sought a judicial declaration to that effect. Without Landmark's agreement to participate in the settlement, it is unclear what amount would be available to pay NECC victims from ARL's insurance coverage. Moreover, since this is a declining policy with its coverage amount being reduced by the costs of defense, without the settlement, it is likely that there would be no coverage, or at least greatly reduced coverage, available to pay NECC victims.

12. It is by no means certain that NECC's tort creditors would be able to realize through litigation the significant sum that ARL has contributed to the NECC estate, and certainly would not be able to realize any recovery whatsoever from ARL without incurring the delay, expense and risks of litigation (including the risk that one significant judgment in favor of a tort claimant would significantly deplete the amounts available to pay any others). Under these circumstances, ARL's contribution is "substantial."

**C. The Plan Releases and Injunction are Essential to the Success of the Plan.**

11. The Plan releases and injunctions apply to ARL and Landmark, and the persons and entities related to them as described in the settlement agreement. ARL and Landmark are to receive global releases and an injunction protecting them from any and all claims by anyone that were related in any way to NECC or the drugs it compounded. The global releases and injunction required under the ARL settlement agreement were to be achieved through confirmation of a plan of reorganization in NECC's bankruptcy case.

12. ARL would not have settled with the Trustee or have waived its rights to defense under the applicable insurance policies if ARL and its employees, affiliates, and agents were not protected from further third party claims brought by the tort claimants who are to be the principal beneficiaries of ARL's contributions through the Plan, and protected from all contribution, indemnity and other claims related to NECC and drugs compounded by it. In that same vein, Landmark would not have agreed to any settlement if there was any risk that any person or entity who was an insured under the applicable insurance policy would seek reimbursement of defense costs to defend any claims against any of them. The only way to eliminate the risk of further defense costs to these insureds was to provide third party releases and an injunction to eliminate the need for them to defend themselves from any claims, and in exchange to secure from the insureds the "policy releases" Landmark required as a condition to settlement. Effectively, *all* of the beneficiaries of the third party releases and injunction are contributors in that Landmark could not have contributed what it intends to contribute without the third party releases of all putative insureds, including those not directly contributing funds towards the settlement. Thus, the third party releases and injunction were critical to the settlement.

13. Throughout the settlement negotiations, the mutual understanding among ARL, Landmark, the mediator, the Trustee, and representatives of both the Official Committee and the Plaintiffs' Steering Committee was that what ARL and Landmark were only willing to negotiate and enter into a settlement on the condition that any settlement was a final settlement of *all* NECC-related liability - not only that of ARL and Landmark, but any potential liability of its related parties, including ARL's officers, directors, employees and other agents and its affiliates. It was with this understanding that ARL agreed to make its significant contribution to the NECC estate.

14. I understand that ARL's significant contribution will be an important addition to a fund to be distributed to NECC's creditors, and that absent ARL's contribution, and those of other parties, NECC's estate would have limited, if any, assets available for distributions. Moreover, as described above, in light of ARL's strong defenses to liability, it is by no means certain that NECC's tort creditors would be able to recover any amounts from, or even to obtain any judgments against ARL if the Plan were not confirmed and the releases and injunction contained therein were not made effective. And even if judgments could be and were obtained, each judgment awarded to an NECC tort creditor would reduce the amount available to pay to other tort creditors, as each claim paid under ARL's insurance policy would reduce the amount available to satisfy other claims, as would the costs of continuing to defend the hundreds of pending cases.


15. For these reasons, I believe that the Plan releases and injunction in favor of ARL, its insurer, and agents and affiliates of each are not only appropriate but are in the best interests of NECC's creditors and are essential to consummation of the proposed Plan.

16. In sum, I, on behalf of ARL, respectfully submit that (i) under the circumstances, the relevant required factors are satisfied, (ii) that the Plan releases and injunction are in the best interest of the NECC estate and its creditors, and (iii) that the settlement, as embodied in the Plan, best provides for the equitable distribution of ARL's substantial contribution to NECC's creditors. I, on behalf of ARL, fully support confirmation of the Plan.

I certify and declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge and belief.



Executed on the 27<sup>th</sup> day of April 2015.

  
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Gregory E. Thomas  
Vice President Business Development  
ARL BioPharma, Inc. d/b/a Analytical Research  
Laboratories